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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,687	02/17/2006	Norbert Heimburger	064781505	2787

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EXAMINER	
KIM, TAEYOON	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

TH

Office Action Summary	Application No.	Applicant(s)	
	10/568,687	HEIMBURGER ET AL.	
	Examiner	Art Unit	
	Taeyoon Kim	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 October 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-35* is/are pending in the application.

4a) Of the above claim(s) *23-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,8,12-16 & 20-22* is/are rejected.

7)☒ Claim(s) *9-11 and 17-19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 February 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4/19/06, 10/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 7-35 are pending.

Election/Restrictions

Applicant's election with traverse of Group I (claims 7-22) in the reply filed on Oct. 19, 2006 is acknowledged. The traversal is on the ground(s) that there is no serious search burden to the examiner to search all three groups of inventions. It is found not persuasive because search burden is not considered for applications entering the US National Stage under 35 U.S.C. §371. Applicant alleges that there would be no burden on the examiner in examining all of the claims at once, relying on M.P.E.P. §802.02. Chapter 800, however, is limited to a discussion of the subject of restriction and double patenting under Title 35 of the United States Code and Title 37 of the Code of Federal Regulations as it relates to national applications filed under 35 U.S.C. 111(a). The discussion of unity of invention under the Patent Cooperation Treaty Articles and Rules as it is applied as an International Searching Authority, International Preliminary Examining Authority, and in applications entering the National Stage under 35 U.S.C. 371 as a Designated or Elected Office in the U.S. Patent and Trademark Office is covered in M.P.E.P. §1850 and is dictated by PCT Rules 13.1 and 13.2. See M.P.E.P. §801. Burden is not a consideration in a finding of lack of inventive unity; rather, according to M.P.E.P. §1850, the only consideration is whether the inventions share a special technical feature.

Applicant's election of orthomyxovirus (group A) and influenza A virus (group B) is acknowledged. Again, the argument of search burden is not a factor for the restriction

requirement under PCT and 35 U.S.C. §371. However, the requirement of species election has been withdrawn due to the lack of prior art upon search.

The requirement is still deemed proper and is therefore made FINAL.

Claims 23-35 have been withdrawn from consideration as being drawn to non-elected subject matter. Claims 7-22 have been considered on the merits.

Drawings

The drawings are objected to because the figures (Figs. 1-8) are not visible. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 and its dependent claims contain a phrase in the first line "...caused by at least one of a virus and a bacterium ...". It is not clear what the subject matter is claimed here. It can be one virus or one bacterium, or both a virus and a bacterium. For examining purpose, it has been interpreted as "at least one of a virus or a bacterium".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 8, 13, 14, 16, 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Caliezi et al. (2000).

Claims 7, 8, 13, 14, 16, 21 and 22 are drawn to a method of treating an infection caused by a virus or a bacterium comprising administering to a subject an effective amount of a composition comprising C1 esterase inhibitor (C1-INH), wherein the virus

or the bacterium comprises at least hemagglutinin or neuraminidase (claim 7); a limitation to the infection being acute (claim 8); a limitation to the composition being administered intravenously (claim 13); a limitation to the subject being a human subject (claim 14); a method of modulating an immune response to a bacterium comprising administering to a subject comprising C1-INH, wherein the bacterium comprsises at least one of hemagglutinin or neuraminidase (claim 16); a limitation to the composition of claim 16 being administered intravenously (claim 21); a limitation to the subject being a human subject (claim 22).

Caliezi et al. teach a method of treating septic shock caused by an acute infection by *E. coli* or *Salmonella typhimurium* comprising administering C1-INH intravenously (see Table 2 at p.102). Caliezi et al. also teach the subject being a human (see Table 3; p.103).

Caliezi et al. do not teach that the *E. coli* or *Salmonella typhimurium* comprises hemagglutinin or neuraminidase. However, it is inherent property that E. coli expresses hemagglutinin as evidenced by Evans et al. (1979).

Since C1-INH has anti-inflammatory activity as taught by Caliezi et al. (p. 92), the administration of C1-INH to a subject would have inherently modulated an immune response caused by the bacterial infection.

M.P.E.P. §2112 states that "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." Atlas Powder Co. *v.* Ireco Inc., 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir.

1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re* Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). >In *In re* Crish, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court held that the claimed promoter sequence obtained by sequencing a prior art plasmid that was not previously sequenced was anticipated by the prior art plasmid which necessarily possessed the same DNA sequence as the claimed oligonucleotides. The court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel." Therefore, a holding of anticipation is clearly required.

Thus, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caliezi et al. (supra) in view of Newman et al. (1993).

Claims 12 and 20 are drawn to the limitation of the bacterium in the method of claims 7 and 16 being *Vibrio cholerae*.

Caliezi et al. teach the limitations of the methods of claims 7 and 16 (see above).

Caliezi et al. do not teach *Vibrio cholerae* causing sepsis and/or septic shock which can be treated by administering C1-INH.

Newman et al. teach that *Vibrio cholerae* strain of bacteria can cause severe sepsis and/or septic shock.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use the method of Caliezi et al. in a patient having a sepsis caused by *Vibrio cholerae* taught by Newman et al.

The skilled artisan would have been motivated to make such a modification because both *E. coli* as well as *Salmonella typhimurium* of Caliezi et al. and *Vibrio cholerae* of Newman et al. cause sepsis and/or septic shock, and administration of C1-INH can be a treatment for sepsis caused by these bacteria.

The person of ordinary skill in the art would have had a reasonable expectation of success in treatment of a patient having sepsis caused by *Vibrio cholerae* because

C1-INH works as an anti-inflammatory agent against the inflammation caused by endotoxins of these bacteria.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caliezi et al. (supra) in view of Gustafson et al. (US 7,014,857 B1).

Claim 15 is drawn to a method of treating an infection caused by a bacterium comprising administering to a subject an effective amount of a composition comprising C1 esterase inhibitor (C1-INH), wherein the bacterium comprises at least hemagglutinin or neuraminidase, and further comprising administering a vaccine against the bacterium.

Caliezi et al. teach the limitations of claim 7 (see above).

Caliezi et al. do not teach the administration of a vaccine against the bacterium.

Gustafson et al. teach the anti-sepsis vaccine to treat sepsis and/or septic shock caused by E. coli. (Abstract and columns 1-4).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to combine C1-INH of Caliezi et al. and the vaccine against the bacteria causing sepsis. Both C1-INH and the anti-sepsis vaccine are used to treat sepsis and/or septic shock caused by bacterial infection.

M.P.E.P. §2144.06 states "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to

form a third composition to be used for the very same purpose. [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also *In re* Crockett, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte* Quadranti, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious).

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

Allowable Subject Matter

Claims 9, 10, 11 and 17-19 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed. Claims 9, 10, 11 and 17-19 are free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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